4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-1031]

Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act." This draft guidance addresses the process through which registrants of drug establishments should submit to FDA reports on the amount of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-D-1031 for "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002; or Policy and Regulations Staff, HFV-6, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Neil Stiber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4128, Silver Spring, MD 20993-0002, 301-796-8944; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, (HFV-210), Rm. 2612, Rockville, MD 20855, 240-402-5745.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act." On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019 (COVID-19). In addition, the CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. Section 3112(e) of the CARES Act (Pub. L. 116-136) added section 510(j)(3) of the FD&C Act (21 U.S.C. 360(j)(3)) to require that each person (including repackers and relabelers) who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.

This draft guidance is intended to assist registrants of drug establishments in submitting to FDA reports on the amount of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution, as required by section 510(j)(3) of the

FD&C Act. The draft guidance addresses the content of reports, the timing of reports, and the process for report submission.

This draft guidance describes the process that should be used for reporting by each person who registers with FDA under section 510 of the FD&C Act with regard to a listed drug (including a finished dosage form product, an active pharmaceutical ingredient, and other listed drugs), except for biological products or categories thereof exempted by an order under section 510(j)(3)(B)). The process described in this guidance applies to such reporting with respect to listed drugs, including medical gases, homeopathic products, products marketed in accordance with requirements under section 505G of the FD&C Act (21 U.S.C. 355h), often referred to as over-the-counter monograph drugs, and animal drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act (21 U.S.C. 360b, 360ccc, and 360ccc-1).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA.

The regulatory citations and associated collections of information that OMB approved are as follows:

- Registrants who own or operate a domestic or foreign establishment that manufactures, prepares, propagates, compounds, or processes a drug must submit to FDA information on the amount of listed drugs that they manufacture, prepare, propagate, compound, or process. Registrants must submit information on the following listed drugs: (1) finished dosage form products, (2) drug products with active pharmaceutical ingredients, and (3) other listed drugs. The collection of information under section 510(j)(3) of the FD&C Act (as added by section 3112 of the CARES Act) on the amount of listed drug products has been approved under OMB control number 0910-0045. FDA is developing an electronic portal for registrants to submit this information.
- FDA requires that applicants submit annual reports for abbreviated new drug applications, biologics license applications, and new drug applications. The collections of information in parts 314 and 601 have been approved under OMB control numbers 0910-0001 and 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: October 27, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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